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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,538	10/23/2003	Michele Sanicola-Nadel	BINA117CN	4018
959	7590	10/18/2005		
LAHIVE & COCKFIELD, LLP. 28 STATE STREET BOSTON, MA 02109			EXAMINER TUNGATURTHI, PARITHOSH K	
			ART UNIT	PAPER NUMBER
			1643	

DATE MAILED: 10/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/693,538

Applicant(s)

SANICOLA-NADEL ET AL.

Examiner

Parithosh K. Tungaturthi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-61 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-41 and 58-60, drawn to an antibody that specifically binds to an epitope in the ligand/receptor binding domain of Cripto, classified in class 530, subclass 387.1.

II. Claim 42 and 49, drawn to a method of modulating growth of tumor cells in vitro in a sample, classified in class 435, subclass 7.1.

III. Claims 43, 44, 50 and 51, drawn to a method of modulating growth of tumor cells in vivo in a subject, classified in class 514, subclass 2, for example.

IV. Claims 45-48 and 52-55, drawn to a method of treating a subject having a tumor that over-expresses Cripto, classified in class 514, subclass 2, for example.

V. Claim 56, drawn to a method of determining whether a tissue expresses Cripto, comprising the step of analyzing tissue from the subject in an immunoassay using an antibody, classified in class 435, subclass 7.1 for example.

VI. Claim 57, drawn to a method of determining whether a cell line overexpresses Cripto, comprising the step of analyzing the cell line in an immunoassay using an antibody, classified in class 435, subclass 7.1 for example.

VII. Claim 61, drawn to a method of treating a subject for a condition associated with undesired cell proliferation, classified in class 424, subclass 9.1 for example.

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2. The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups II-VII are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success. In the instant case, Group II is drawn to a method of modulating growth of tumor cells in vitro in a sample, Group III is drawn to a method of modulating growth of tumor cells in vivo in a subject, Group IV is drawn to a method of treating a subject having a tumor that over-expresses Cripto, Group V is drawn to a method of determining whether a tissue expresses Cripto, comprising the step of analyzing tissue from the subject in an immunoassay using an antibody, Group VI is drawn to a method of determining whether a cell line overexpresses Cripto, comprising the step of analyzing the cell line in an immunoassay using an antibody and Group VII is drawn to a method of treating a subject for a condition associated with undesired cell proliferation. Therefore, each method is divergent in materials and steps. The examination of all groups would require different searches in the U.S. PATENT SHOES and the scientific literature and would require the consideration of different patentability issues. Thus Inventions II-VII are separate and distinct in having different method steps and different endpoints and are patentably distinct.

Inventions I and II-VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of

group I can be used in a materially different method such as in immunoassays in addition to the materially different methods of groups II-VII.

Election of species within Group I-VII

3. This application contains claims directed to the following patentably distinct species of the claimed invention I-VII

If any of the groups I-VII is elected, the applicant is required to elect one species from the following list:

Species a) SEQ ID NO:1

Species b) SEQ ID NO:2

Please note that the applicant is required to select ONE antibody from the list claimed that is specific to either SEQ ID NO:1 or SEQ ID NO:2.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 42-48 are generic.

The species discussed above patentably distinct because of their distinct properties including the differences in their structure and function.

Election of species within Group II-IV

4. This application contains claims directed to the following patentably distinct species of the claimed invention II-IV

If any of the groups II-IV is elected, the applicant is required to elect one species from the following list:

- Species a) breast
- Species b) testicular
- Species c) colon
- Species d) lung
- Species e) ovary
- Species f) bladder
- Species g) uterine
- Species h) cervical
- Species i) pancreatic
- Species j) stomach

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 42-48 are generic.

The species discussed above patentably distinct because of their distinct properties including the differences in their pathologies and modes of administration.

5. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

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is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, because these inventions are distinct for the reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper.

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7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

8. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain

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dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Parithosh K. Tungaturthi whose telephone number is 571-272-8789. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
Parithosh K. Tungaturthi, Ph.D.
Ph: (571) 272-8789



LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER